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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,910	03/30/2001	Daniel J. Balbierz	13724-845	7532

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EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 11/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/823,910	Applicant(s) BALBIERZ ET AL. af	
	Examiner Peter J Vrettakos	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-58, 63-66, 69, 74-91, and 101-104 is/are rejected.
- 7) ☒ Claim(s) 59-62, 67, 68, 70-73 and 92-100 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 depends upon itself.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-39, 42-46, 57-58, 63, 65, 69, 74-77, 78-91, and 101-104 are rejected under 35 U.S.C. 102(b) as being anticipated by Gough et al. ('847).

Independent claims 1, 101, 102, 104

Gough et al. (Gough) discloses a method for treating a tumor comprising:

providing a tissue biopsy and treatment apparatus especially in figure 3 comprising an elongated delivery device (10) including a lumen (14); a deployable sensor array (24) including a plurality of resilient members (18) deployable with curvature (see figure 3), the sensor array having a geometric configuration (depicted in

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figure 3) adapted to volumetrically sample tissue at a tissue site or multiple tissue sites to differentiate or identify tissue including tumor boundaries (col. 4:63-67) at the tissue site(s) during an energy delivery interval (col. 6: 28-33); an energy delivery device (12,14,16, 20) coupled to (or comprising) the resilient members (18);

introducing the apparatus into a target tissue site (col. 2:22-25);

distinguishing a tissue type (ex. tumorous) utilizing the sensor array (col. 4:63-67 and col. 6:33-34);

positioning or *maneuvering* the energy delivery device utilizing tissue type information derived from the sensor array to ablate or necrose a tumor volume (col. 6:64-66);

delivering energy from the energy delivery device to ablate or necrose at least a portion of the tumor volume (col. 7:5-7);

determining an amount of tumor volume ablation utilizing the sensor array (col. 6:28-33).

Re: claim 102, Gough discloses *comparing* sequential measurements in order to determine ablation amounts in column 6 lines 28-33 ("(iii) whether or not further ablation is needed").

Dependent claims

Re: claims 2 and 6, Gough discloses monitoring tissue volumes (col. 6: 28-33, iv).

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Re: claims 6-8, 14-15, 25, 27, and 28, Gough discloses monitoring at least a first and second tissue volume represented by tissue volumes proximal to each sensor (24, fig. 3). Further, Gough discloses monitoring tissue volume within a tumor (28) and outside ("adjacent") a tumor. Note column 8 lines 57-61. This specific disclosure makes inherent that differentiating between tissue types is occurring between a selected tissue mass and a non-selected tissue mass. Also, made inherent is that a determination of a healthy tissue (non-tumorous, non-selected) ablative margin (analogous to tumor boundary) is made by the logic resources (col. 9:49-57). Lastly, note that Gough establishes equivalency between a tumor and a selected tissue mass in column 4 lines 63-67.

Re: claims 9-13, 16, and 89-91, Gough discloses a multiplexer to measure and compare parameters at the numerous sensors (24) each providing measurements including temperature from different tissue volumes. Fig. 3 depicts sensors (24) along different portions of delivery device (10). Therefore, monitoring will occur at numerous locations throughout the delivery device. Further, some of the sensors are in closer lateral proximity to the energy delivery device (14) than others (clearly illustrated in figure 3).

Re: claims 17, Gough discloses a primary sensor array portion (24, figure 3, attached to 14) and a secondary sensor array portion (24, figure 3, attached to 16).

Re: claims 3,5, 29, 30, 34, 35, and 76, Gough discloses logic resources or processor (38, fig. 9, 50. fig. 10) coupled to a power source (20). Power is adjusted in response to an input from the sensor array (col. 6:48-54).

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Re: claims 4, 26, 32, 38, 45, 77, and 85-86, tissue temperature or tissue impedance is monitored (col. 6: 42-44).

Re: claims 18,19,21, 33,37,74, and 87-88, Gough discloses locating a tumor volume (boundaries) utilizing the sensor array (col. 4:63-67 and col. 6:33-34).

Re: claims 20,22,and 46, Gough discloses positioning the energy delivery device within or relative to the tumor to controllably ablate the target volume (col. 6:64-66).

Re: claims 23, 24, 39, 42, 44, 64, 66, and 103, Gough discloses determining the amount of tissue necrosis or a treatment endpoint utilizing the sensor array (col. 6: 28-33).

Re: claims 31 and 36, Gough discloses a database (col. 10:32-33).

Re: claim 43, Gough discloses titrating a tissue treatment based on information derived from a tissue property (col. 6:28-33, especially iii).

Re: claims 57, 58, and 69, Gough discloses chemotherapeutic marking agents (col. 9:22-30).

Re: claim 63, 65, 83, 84, Gough discloses infusion of marking agents (conductivity enhancement mediums) to enhance delivery of energy and thermal injury to the tumor (col. 9:25-28).

Re: claim 75, Gough discloses RF electrodes (col. 6:10-13).

Re: claims 79-81, Gough discloses tapered resilient members (18) with different changing directions of travel in tissue when advanced from the elongated delivery device to a selected tissue site as depicted in figure 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 47-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Hoey et al. ('722).

Gough neglects to disclose *baseline measurements*.

Hoey et al. (Hoey) discloses an analogous electrode tissue ablation method in which *baseline impedance measurements* (232) are taken as depicted in figure 11. Further, Hoey discloses comparing (226,240) impedance measurements throughout the surgery and adjusting (228,246) energy delivery parameters (RF power), accordingly, which further affect tissue ablation time and volume.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Gough in view of Hoey by including as a method step, that of obtaining and using impedance measurements to guide effective surgery. The motivation would be to "safeguard the patient and the apparatus," as submitted in Hoey col. 23:20-21.

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Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Edwards ('528).

Gough neglects to disclose *making a diagnosis based on measured a tissue property*.

Edwards discloses an analogous electrode tissue ablation method in which a *diagnosis based on a measured tissue property (impedance) is made*. Note column 9:9-20; iii.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Gough in view of Edwards by making a diagnosis using measurements of tissue property. The motivation would obviously be to afford the surgeon insight with regards to the condition of the patient in order to develop an effective plan for surgical intervention.

Allowable Subject Matter

Claims 59-62, 67-68, 70-73, and 92-100 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos
November 25, 2002

PV

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER